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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,888	10/06/2003	Nader Najafi	IB-12	3813
27127 7590 08/10/2009 HARTMAN & HARTMAN, P.C. 552 EAST 700 NORTH VALPARAISO, IN 46383				
EXAMINER MALLARI, PATRICIA C				
ART UNIT		PAPER NUMBER		
3735				
NOTIFICATION DATE		DELIVERY MODE		
08/10/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

domenica@hartmaniplaw.com  
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### Office Action Summary

**Application No.**

10/679,888

**Applicant(s)**

NAJAFI ET AL.

**Examiner**

PATRICIA C. MALLARI

**Art Unit**

3735

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-5, 8, 9, 17-21 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 8, 9, 17-21 and 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This is final Office action. No new grounds of rejection have been presented.

#### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of the prior-filed provisional applications, Application Nos. 60/416406, 60/416407, 60/416408, and 60/416409, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The disclosures fail to describe at least injecting the sensor package so as to deliver said sensor package into a first pulmonary artery, wherein blood flow through the first pulmonary artery delivers said sensor package into a second pulmonary artery with a smaller diameter than said first pulmonary artery, the second pulmonary artery being sufficiently small to prevent further movement of said

sensor package and anchor said sensor package therein" as claimed in independent claim 30.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 9, 17-21, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication No. 2002/0151816 to Rich et al. in view of US Patent No. 7,147,604 to Allen et al. and US Patent No. 4,869,263 to Segal et al. Regarding claim 30, Rich teaches a hermetic sensor package and a method of delivering the package to monitor pulmonary artery pressure within a patient. The package has a diameter and is adapted to be implanted into a pulmonary artery. The package comprises at least one sensing, said sensing device comprising at least one pressure sensor (see entire document, especially figs. 4, 15, 16; paragraphs 49, 65, 68, 89 of Rich). The method comprises injecting the sensor package so as to deliver the package into a blood vessel (see entire document, especially paragraph 77 of Rich), wherein the blood vessel is sufficiently small to prevent further movement of the sensor package and to anchor the sensor package therein (see entire document, especially figs. 15, 16 of Rich). The blood vessel is blocked, at least in part, with the sensor

package, and the sensor package is operated while the vessel remains blocked by the sensor package to chronically monitor pressure in the vessel (see entire document, especially figs. 15, 16; paragraphs 77, 78 of Rich), wherein the sensor may be used to monitor pulmonary artery pressure (see entire document, especially paragraph 89 of Rich). Rich lacks injecting the sensor package into a first pulmonary artery, wherein blood flow through the first artery delivers the sensor package into a second pulmonary artery with a smaller diameter than the first.

However, Allen teaches monitoring pulmonary artery pressure, wherein a sensor package is injected into a site with the patient's vasculature so as to become lodged into a minor pulmonary artery or pulmonary capillary (see entire document, especially col. 7, lines 39-48 of Allen). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to lodge the sensor of Rich in a pulmonary artery or capillary, since Rich teaches being injected so as to measure pulmonary artery pressure, and Allen teaches a pulmonary artery or capillary as an appropriate position for an implantable pressure sensor for monitoring a pulmonary pressure sensor. Rich, as modified, still lacks injecting the sensor package into a first pulmonary artery, wherein blood flow through the first artery delivers the sensor package into the second pulmonary artery, wherein the second pulmonary artery has a smaller diameter than the first.

However, Segal teaches lodging a device in a second pulmonary artery, wherein the device is first injected into a first pulmonary artery 129, and the blood flow through the first pulmonary artery delivers the device into the second pulmonary artery 131 and

the second pulmonary artery has a smaller diameter than the first (see entire document, especially fig. 11; col. 5, lines 45-53 of Segal). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Segal with that of Rich, as modified, since Rich, as modified, teaches delivering and lodging the sensor to a pulmonary artery, and Segal describes an appropriate method of delivering and lodging a device in a pulmonary artery.

Regarding claim 2, implantation of the sensor package is performed for diagnosis of hypertension, wherein clearly, if the pulmonary arterial pressure is being monitored, then the determination of hypertension based on such a pressure is of pulmonary hypertension (see entire document, especially paragraph 81 of Rich; col. 1, lines 15-64 of Allen).

Regarding claim 3, the pressure sensor is a capacitive sensor (see entire document, especially figs. 1, 3-5; paragraph 57 of Rich).

Regarding claim 9, a readout device not adapted to be implanted in the patient is used to telecommunicate with and/or telepower said sensing device (see entire document, especially figs. 1, 12; paragraphs 49-51, 71 of Rich).

Regarding claim 17, the injection of the sensor package into the pulmonary artery or similar vessel is a surgical technique (see entire document, especially col. 3, lines 63-65; col. 7, lines 39-48 of Allen; col. 5, lines 42-66 of Segal).

Regarding claim 18, the injection of the sensor package is a minimally invasive outpatient technique (see entire document, especially col. 3, lines 63-65; col. 7, lines 39-48 of Allen; col. 5, lines 42-66 of Segal).

Regarding claim 19, a catheter delivery technique is used to inject the sensor package (see entire document, especially col. 3, lines 63-65; col. 6, line 31-col. 7, line 48 of Allen).

Regarding claim 20, the sensor package comprises an anchoring mechanism (see entire document, especially figs. 15, 16; paragraphs 77, 78 of Rich).

Regarding claim 21, the sensor package is anchored to the artery by the diameter of the sensor package (see entire document, especially figs. 15, 16; paragraphs 77, 78 of Rich), wherein the package includes spring cage 112 or spring arms 116.

Regarding claims 32 and 33, at least a portion of the sensor package is coated with at least one coating (see entire document, especially paragraph 73 of Rich), wherein the coating may be parylene, polymer, or titanium

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rich in view of Allen and Segal, as applied to claims 2, 3, 9, 17-21, 30, 32, and 33 above, and further in view of US Patent 6,252,548 to Ishikawa. Regarding claim 4, Rich, as modified, teaches using a capacitor for temporary power storage but lacks a battery. However, Ishikawa teaches an implantable device comprising a power storage unit, wherein the power storage unit may be a capacitor, battery, or combination thereof (see entire document, especially fig. 5; col. 6, lines 43-65 of Ishikawa). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a

battery in place of or in addition to the capacitor in the method of Rich, as modified, as it would merely be the substitution of one known power storage unit for another.

Regarding claim 5, wireless means for recharging the battery are included (see entire document, especially fig. 5; col. 6, lines 43-65 of Ishikawa).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rich in view of Allen and Segal, as applied to claims 2, 3, 9, 17-21, 30, 32, and 33 above, and further in view of US Patent No. 56,409,674 to Brockway et al. Rich, as modified, discloses that the data analysis circuitry may be included (see entire document, especially paragraph 50 of Rich) but is silent as to the details of the data analysis. Brockway further discloses that the determination of  $dP/dt$  is useful in monitoring the work load of the heart (see entire document, especially col. 1, line 38-col. 2, line 6 of Brockway). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention for the data analysis circuitry of Rich, as modified, to determine  $dP/dt$ , as disclosed in Brockway, since Rich, as modified, discloses performing data analysis and Brockway further describes analyzing the pressure signal to determine  $dP/dt$ , wherein  $dP/dt$  is useful in determining the work load of the heart, among other things.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Rich and Segal, as applied to claims 2, 3, 9, 17-21, 30, 32, and 33 above, and further in view of US Patent No. 5,662,712 to Pathak et al. Regarding



claims 31 and 32, Rich, as modified, lacks encapsulating the sensor package with cell growth to stabilize the sensor package. However, Pathak discloses a device implanted in an artery, wherein cell growth and encapsulation of the device are encouraged to stabilize/anchor the device (see entire document, especially col. 6, lines 1-24 of Pathak). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include cell growth and encapsulation as shown in Pathak in the method of Rich, as modified, in order to further stabilize or anchor the sensor.

### ***Response to Arguments***

Applicant's arguments filed 4/27/09 have been fully considered but they are not persuasive.

Applicants argue that Rich is a 102(e)/103 reference and the applicants' invention and Rich were commonly assigned. However, Rich is not a 102(e)/103 reference. The provisional applications fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application (see above for details). Since none of the provisional applications 60/416406, 60/416407, 60/416408, and 60/416409 provide such support, the instant application is not afforded the priority date of any of the provisional applications. The effective filing date of the instant application is 10/6/03. The publication date of Rich is 10/17/02, which makes Rich prior art under 102(a) not 102(e). Therefore, common assignment is insufficient to disqualify Rich as prior art. The rejections stand.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/  
Primary Examiner, Art Unit 3735